C. Remarks

The claims are 2-14 and 16-41, with claims 2, 19 and 20 being independent. Claim 1 has been cancelled without prejudice or disclaimer of the subject matter. Support for the amendment to claim 2 may be found on page 4, paragraph [0035] of the published specification, U.S. Patent Application Publication No. 2005/0136104 (the "104 publication"). Applicants submit that no new matter has been added. Reconsideration of the present claims is respectfully requested.

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Cancellation of claim 1 renders the rejection of this claim moot.

Claims 1-14 and 16-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Borkan (U.S. Patent No. 4,935,243) in view of Tanner (U.S. Patent No. 6,340,473), Hutchison (U.S. Patent No. 5,817,323) and Stroud (U.S. Patent No. 5,554,385). Applicants respectfully traverse this rejection.

The present invention is directed to a gelatin capsule formed from a capsule film having a thickness not exceeding 0.030 inches, and a capsule shell having an end composition comprising at least one gelatin, plasticizer and at least one hydroxypropylated, substantially ungelatinized starch. By virtue of this constitution, it is possible to provide high water content, chewable soft gelatin capsules with improved organoleptic properties. The present invention allows for the manipulation of the origin, bloom strength and melting points of gelatins and mixtures of gelatins, the use of hydroxypropylated, substantially ungelatinized starch as a water retention agent, the fabrication of thinner than expected gelatin films for use in the encapsulation process, only partial drying to a high end water

content and dusting of the capsules with an anti-stickiness surface treatment agent.

Applicants created the capsule of the presently claimed invention, which is dried to a relatively high water content. As set forth in the amended independent claims (and therefore applicable to all dependent claims), the capsule shell has an end water content of 9.5% to 11.5%. Unlike traditional gelatin capsules, which are typically dried to 6% to 8% water, the presently claimed invention is dried to a water content of 9.5% to 11.5%. Pages 3-4, paragraph [0035] of the '104 publication. This higher water content has improved mouthfeel and chewability without the typical drawbacks of higher water content, like stickiness or clumping together. Page 4, paragraph [0035] of the '104 publication. This advance over the prior art is achieved through a process of lightly tumble drying the capsules, and in some case, using a dusting agent. Page 4, paragraph [0035]-[0036] of the '104 publication.

A research goal behind the instant invention was to increase heat stability, at least in part by exploring gelatins of higher bloom strength and mammalian origins, while maintaining the excellent organoleptics seen in fish gelatins with low bloom strengths, low melting points, and/or, as explained above, high water contents. Page 2, paragraph [0010] of the '104 publication. Additionally, Applicants found that higher bloom strengths allow for the casting of thinner films, which results in faster dissolution/disintegration of the capsule shell, and for stronger and more robust ribbons. Page 3, paragraph [0033] of the '104 publication. Therefore, a unique aspect of the presently claimed invention is that the gelatin capsules are able to maintain both robust seals and thin walls (in accordance with the

newly added claim limitation) by virtue of the combination of stronger gelatins and hydroxypropylated, substantially ungelatinized starch. Id.

Borkan discloses a chewable softgel capsule containing gelatin and a plasticizer (including glycerol); however, as noted by the Examiner, Borkan does not teach or suggest the inclusion of a modified starch, such as hydroxypropylated, ungelatinized starch, and a capsule having a film thickness not exceeding 0.030 inches. The hydrogenated starch hydrolysate used therein (described at column 4, line 5, to column 5, line 11) is characterized as a mixture of sugars, hydrogenated sugars, polyols and sugar alcohols. This component in no way equates with the high molecular weight, polymeric starch employed in the subject invention. Additionally, Borkan fails to disclose or suggest the end water content of the presently claimed invention. In fact, Borkan teaches away from said water content by disclosing that the water content of the shell is between 15%-30% to aid in its rapid dissolution. Column 3, lines 59-63. Therefore, Applicants submit that Borkan does not render the present invention obvious.

Tanner is cited by the Examiner for its disclosure of a soft capsule shell comprising modified starch, such as hydroxypropylated maize starch, plasticizer, such as glycerin and sorbitol, and a resulting capsule having a shell thickness of 0.030 inches. However, as previously noted, there is no reference in Tanner to the use of gelatin and, indeed, the disclosure states that the intention is to obviate the requirement for gelatin. As such, this reference teaches away from the present invention wherein modified starch and plasticizer are combined with gelatin. In other words, one of ordinary skill in the art would not be motivated to combine this reference with Borkan to achieve the subject invention

(which requires the use of gelatin) nor would one of ordinary skill in the art regard any of its teachings as conventional in the art of making capsule shells containing gelatin. Because of these differences, one would not combine Tanner and Borkan to expect that a shell containing gelatin like that of the present invention would achieve the same ribbon thickness as the capsule of Tanner. Additionally, Tanner merely discloses the percentage water content in the wet composition of the shell and fails to disclose or suggest a water content for the end product.

Hutchison and Stroud, likewise, do not remedy the deficiencies of Borkan in view of Tanner. Hutchison discloses a soft gelatin capsule comprising a gelatin and a secondary matrix former, but fails to disclose or suggest a hydroxypropylated or a substantially ungelatinized starch. Stroud discloses soft gelatin capsules wherein some of the gelatin is replaced by starch. However, Stroud fails to teach or suggest using a hydroxypropylated or ungelatinized starch as part of the capsule composition and is limited to a disclosure of starches of high amylose content. While Stroud discloses a capsule wall having a thickness of about 0.030 inches, the present invention claims a capsule wall not exceeding 0.030 inches. Therefore, as disclosed, *inter alia*, in Tables 2 and 12 of the published specification of the present invention, the ribbon may be 0.025 inches or even 0.015 inches thick. In addition, unlike the presently claimed invention, the capsule shell of Stroud has a 6% water content. Therefore, Applicants submit that neither Hutchison nor Stroud discloses or suggests the gelatin capsule of the claimed invention, and specifically, neither discloses or suggests a capsule having a final end water content of 9.5% to 11.5%.

In sum, the presently claimed invention is not rendered obvious by the cited references, whether considered separately or in any permissible combination. Both Borkan and Hutchison fail to disclose or suggest at least the use of hydroxypropylated, substantially ungelatinized starch, a ribbon thickness of less that 0.030 inches, and a water content of the capsule of 9.5% to 11.5%. Further, Tanner and Stroud fail to remedy these deficiencies. For at least these reasons, Applicants submit that the present invention is not rendered obvious and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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